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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,598	09/05/2003	David P. Davis	P1981R1P1	7980
9157	7590	05/30/2006	EXAMINER	
GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			GODDARD, LAURA B	
			ART UNIT	PAPER NUMBER
			1642	
DATE MAILED: 05/30/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/656,598	Applicant(s) DAVIS ET AL.	
	Examiner Laura B. Goddard, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-102 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-102 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, drawn to an isolated **polynucleotide**, classified in class 536, subclass 23.5.

Additionally, Applicants must elect a single nucleic acid sequence SEQ ID NO: 1, 3, or 5 and the corresponding polypeptide SEQ ID NO: 2, 4, or 6 that it encodes, as each sequence presents a structurally and functionally *distinct* invention not a species.

- II. Claims 10-13, 58-61, drawn to an isolated **polypeptide**, classified in class 530, subclass 350.

Additionally, Applicants must elect a single polypeptide sequence SEQ ID NO: 2, 4, or 6 and the corresponding nucleotide SEQ ID NO: 1, 3, or 5 that encodes it, as each sequence presents a structurally and functionally *distinct* invention not a species.

- III. Claims 14-28, 58-61, drawn to an **antibody**, classified in class 530, subclass 387.1.

Additionally, Applicants must elect a single polypeptide sequence SEQ ID NO: 2, 4, or 6 that the antibody binds and the corresponding nucleotide SEQ ID NO: 1, 3, or 5 that encodes the polypeptide, as each sequence presents a structurally and functionally *distinct* invention not a species.

- IV. Claims 29-33, drawn to an isolated **polynucleotide** comprising a sequence that **encodes an antibody**, classified in class 536, subclass 23.53.

Additionally, Applicants must elect a single polypeptide sequence SEQ ID NO: 2, 4, or 6 that the antibody binds and the corresponding nucleotide SEQ ID NO: 1, 3, or 5 that encodes the polypeptide, as each sequence presents a structurally and functionally *distinct* invention not a species.

- V. Claims 34-43, 58-61, drawn to an isolated **oligopeptide** which binds to a polypeptide, classified in class 530, subclass 300.

Additionally, Applicants must elect a single polypeptide sequence SEQ ID NO: 2, 4, or 6 which the oligopeptide binds and the corresponding nucleotide SEQ ID NO: 1, 3, or 5 that encodes the polypeptide, as each sequence presents a structurally and functionally *distinct* invention not a species.

- VI. Claims 44-53, 58-61, drawn to a **TASK binding organic molecule** which binds to a polypeptide, classified in class 530, subclass 300.

Additionally, Applicants must elect a single polypeptide sequence SEQ ID NO: 2, 4, or 6 which the TASK binding organic molecule binds and the corresponding nucleotide SEQ ID NO: 1, 3, or 5 that encodes the polypeptide, as each sequence presents a structurally and functionally *distinct* invention not a species.

- VII. Claims 54-57, 58-61, drawn to a **TASK binding interfering RNA (siRNA)** which binds to a nucleic acid, classified in class 536, subclass 24.5.

Additionally, Applicants must elect a single nucleic acid sequence SEQ ID NO: 1, 3, or 5 which the TASK binding interfering RNA binds and the corresponding polypeptide SEQ ID NO: 2, 4, or 6 that is encoded by the polynucleotide, as each sequence presents a structurally and functionally *distinct* invention not a species.

- VIII. Claims 62-90, 101-102, drawn to a method of inhibiting the growth of a cancer cell that expresses a polypeptide, a method of therapeutically treating a mammal having a tumor that expresses a polypeptide, and a

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method for treating or preventing a cell proliferative disorder associated with increased expression or activity of a polypeptide, classified in class 514, subclass 2.

Additionally, Applicants must elect a single polypeptide sequence SEQ ID NO: 2, 4, or 6 and the corresponding nucleotide SEQ ID NO: 1, 3, or 5 that encodes it, as each sequence presents a structurally and functionally *distinct* invention not a species.

Additionally, Applicants must elect a single type of molecule contacted to the cancer cell or administered to a mammal: antibody (includes anti-TASK polypeptide antibody), oligonucleotide (includes antisense oligonucleotide), siRNA (includes TASK siRNA), oligopeptide (includes TASK binding oligopeptide), or organic molecule (includes TASK binding organic molecule), as each type of molecule presents a structurally and functionally *distinct* invention not a species. Claims 62-90, 101-102 will be examined as drawn to the elected invention.

IX. Claims 91-94, drawn to a method of determining the presence of a polypeptide in a sample, classified in class 435, subclass 7.1 and 6.

Additionally, Applicants must elect a single polypeptide sequence SEQ ID NO: 2, 4, or 6 and the corresponding nucleotide SEQ ID NO: 1, 3, or 5 that encodes it, as each sequence presents a structurally and functionally *distinct* invention not a species.

Additionally, Applicants must elect a single type of molecule exposed to the sample: antibody, oligonucleotide, siRNA, oligopeptide, or organic molecule, as each type of molecule presents a structurally and functionally *distinct* invention not a species.

- X. Claims 95, 96, 98-100, drawn to a method of diagnosing the presence of a tumor in a mammal comprising detecting the level of **expression of a gene** encoding a polypeptide, wherein the step of detecting comprises employing an **oligonucleotide** in an *in situ* hybridization or RT-PCR, and a method of diagnosing the presence of a tumor in a mammal comprising detecting the **polynucleotide** in the sample, classified in class 435, subclass 6.

NOTE: there is no antecedent basis for "said siRNA or oligonucleotide" in claim 98.

Additionally, Applicants must elect a single nucleic acid sequence SEQ ID NO: 1, 3, or 5 and the corresponding polypeptide SEQ ID NO: 2, 4, or 6 that it encodes, as each sequence presents a structurally and functionally *distinct* invention not a species.

Additionally, Applicants must elect a single type of molecule exposed to the sample: oligonucleotide or siRNA, as each type of molecule presents a structurally and functionally *distinct* invention not a species. CLAIMS 95, 96, 98-100 will be examined as drawn to the elected invention.

- XI. Claims 95, 97-100, drawn to a method of diagnosing the presence of a tumor in a mammal comprising contacting a test sample of tissue cells obtained from said mammal with an **antibody**, and said method comprising detecting the level of expression of a gene encoding a polypeptide wherein the step of detecting comprises employing an **antibody** in immunohistochemistry analysis, classified in class 435, subclass 7.1.

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Additionally, Applicants must elect a single polypeptide sequence SEQ ID NO: 2, 4, or 6 and the corresponding nucleotide SEQ ID NO: 1, 3, or 5 that encodes it, as each sequence presents a structurally and functionally *distinct* invention not a species.

XII. Claims 98-100, drawn to a method of diagnosing the presence of a tumor in a mammal comprising detecting the **polypeptide** in a test sample of tissue cells obtained from said mammal comprising contacting the test sample with an **oligopeptide or organic molecule**, classified in class 435, subclass 7.1.

Additionally, Applicants must elect a single polypeptide sequence SEQ ID NO: 2, 4, or 6 and the corresponding nucleotide SEQ ID NO: 1, 3, or 5 that encodes it, as each sequence presents a structurally and functionally *distinct* invention not a species.

Additionally, Applicants must elect a single type of molecule contacted with the sample: oligopeptide or organic molecule, as each type of molecule presents a structurally and functionally *distinct* invention not a species.

The inventions are distinct, each from the other because of the following reasons:

The DNA of Group I is related to the protein of Group II by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays.

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Furthermore, searching the inventions of Groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate database. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequences of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. The scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above: furthermore, a search of the nucleic acid molecules of Group I would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of Group II. As such, it would be burdensome to search the inventions of Groups I and II.

The polypeptide of Group II and the antibody of Group III are patentably distinct for the following reasons:

While the inventions of both Group II and Group III are polypeptides, in this instance the polypeptides of Group II represent various proposed cell cycling protein, whereas the polypeptide of Group III encompasses antibodies including IgG which

comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily determining regions (CDR) that function to bind an epitope. Thus the polypeptides of Group II and the antibodies of Group III are structurally distinct molecules; any relationship between a polypeptide of Group II and an antibody of Group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

In this case, the polypeptides of group II encompass large molecules which contain potentially hundreds of regions to which an antibody may bind, whereas the antibody of Group III is defined in terms of its binding specificity to a small structure within the sequences encompassed by Group II. Furthermore, searching the inventions of Group II and Group III would impose a serious search burden. The inventions have separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of Group III. Furthermore, antibodies which bind to an epitope of a polypeptide of Group II may be known even if a polypeptide of Group II is novel. In addition, the technical literature search for the polypeptides of Group II and the antibody of Group III are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

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The polynucleotide of Group I and the antibody of Group III are patentably distinct for the following reasons:

The antibody of Group III includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily determining regions (CDRs). Polypeptides, such as the antibody of Group III which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Group I will not encode an antibody of Group III, and the antibody of Group III cannot be encoded by a polynucleotide of Group I. Therefore, the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of Group I and Group III would impose a serious search burden since a search of the polynucleotides of Group I would not be used to determine the patentability of any antibody of Group III, and vice-versa.

The polynucleotide of Group IV does not encode for the protein of Group II and structurally and functionally distinct from the polynucleotides of Groups I and VII, the oligopeptides of Group V, the antibody of Group III, and organic molecule of Group VI

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for the reasons set forth above. Therefore, a search of the polynucleotide of Group IV would not be coextensive with the polynucleotides of Groups I and VII, the polypeptide or peptides of Groups II and V, the antibody of Group III, and organic molecule of Group VI, and would be burdensome to search together.

The oligopeptide of Group V is structurally and functionally distinct from the polypeptides of Groups II, antibodies of Group III, polynucleotides of Groups I, IV, and VII, and organic molecule of Group VI. Therefore, a search of Groups V and I-IV, VI-VII would not be coextensive and would be burdensome to search together.

The TASK organic molecule of Group VI is structurally and functionally distinct from the polynucleotides, peptides, polypeptides, antibodies, siRNA of Groups I-V and VII. Therefore, a search of Groups VI and Groups I-V and VII would not be coextensive and would be burdensome to search together.

The TASK siRNA of Group VII is structurally and functionally distinct from the polynucleotides of Groups I and IV and does not encode for the polypeptides, antibodies, oligopeptides, or organic molecules of Groups II, III, V, and VI. Therefore, a search of Groups VII and Groups I-VI would not be coextensive and would be burdensome to search together.

The inventions of Groups VIII-XII are materially distinct methods which differ at least in objectives, method steps and/or reagents. Each of the groups employs chemically distinct reagents to accomplish same or different objectives that comprise different method steps, reagents and/or dosages and/or schedules used, response

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variables, and criteria for success. Searching all of the groups with all of the different variables would invoke a high burden of search.

Inventions III and VIII, IX, XI are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antibody of Group III can be used in affinity chromatography or to produce anti-idiotypic antibodies.

Inventions V and VIII, IX, XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the oligopeptide of Group V can be used in affinity chromatography or to produce antibodies.

Inventions VI and VIII, IX, XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the organic molecule of Group VI can be used in affinity chromatography or to produce antibodies.

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Inventions VII and XIII, IX, X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the siRNA molecule of Group VII can be used to inhibit RNA, in affinity chromatography, or for hybridization assays.

The product of Groups I, II, and IV are not used in the methods of Groups VIII-XII. The product of Group III is not used in the methods of Groups X and XII. The product of Group V is not used in the methods of Groups X and XI. The product of Group VI is not used in the methods of Groups X and XI. The product of Group VII is not used in the method of Groups XI and XII.

Because these inventions are distinct for the reasons given above and the search required for one Group is not required for any other Group, and because some Groups have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final

rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

SPECIES ELECTION

Species Election for Group III

A. This application contains claims directed to the following patentably distinct species of conjugate: **growth inhibitory agent (claim 19) or cytotoxic agent (claim 20)**. The species are independent or distinct because each conjugate is structurally and functionally distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 14 is generic.

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B. This application contains claims directed to the following patentably distinct species of cytotoxic agent: **toxin, antibiotic, radioactive isotope, or nucleolytic enzyme (claim 21)**. The species are independent or distinct because each cytotoxic agent is structurally and functionally distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 14 is generic. **Claims 22 –24 will be examined as drawn to the elected species.**

Species Election for Group V

C. This application contains claims directed to the following patentably distinct species of conjugate: **growth inhibitory agent (claim 36) or cytotoxic agent (claim 37)**. The species are independent or distinct because each conjugate is structurally and functionally distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 34 is generic.

D. This application contains claims directed to the following patentably distinct species of cytotoxic agent: **toxin, antibiotic, radioactive isotope, or nucleolytic enzyme (claim 38)**. The species are independent or distinct because each cytotoxic agent is structurally and functionally distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 34 is generic. **Claims 39-41 will be examined as drawn to the elected species.**

Species Election for Group VI

E. This application contains claims directed to the following patentably distinct species of conjugate: **growth inhibitory agent (claim 46) or cytotoxic agent (claim 47)**. The species are independent or distinct because each conjugate is structurally and functionally distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 44 is generic.

F. This application contains claims directed to the following patentably distinct species of cytotoxic agent: **toxin, antibiotic, radioactive isotope, or nucleolytic enzyme (claim 48)**. The species are independent or distinct because each cytotoxic agent is structurally and functionally distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 44 is generic. **Claims 49-51 will be examined as drawn to the elected species.**

Species Election for Group VIII

G. This application contains claims directed to the following patentably distinct species of conjugate: **growth inhibitory agent (claim 66, 81) or cytotoxic agent (claim 67, 82)**. The species are independent or distinct because each conjugate is structurally and functionally distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 62 and 77 are generic.

H. This application contains claims directed to the following patentably distinct species of cytotoxic agent: **toxin, antibiotic, radioactive isotope, or nucleolytic enzyme (claim 68, 83)**. The species are independent or distinct because each cytotoxic agent is structurally and functionally distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 62 and 77 are generic. **Claims 69-71 and 84-86 will be examined as drawn to the elected species.**

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

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is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura B Goddard, Ph.D.
Examiner
Art Unit 1642


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER